market unit and NZ$ shares, and a decline in total NZ$ sales. The second strategy resulted in a rapid decline of brand product market unit and NZ$ market shares.

PHP25

DIFFERENTIAL EFFECTS OF TWO PHARMACEUTICAL COST CONTAINMENT POLICIES ON OUTPATIENT PRESCRIPTION DRUG EXPENDITURES IN KOREA

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OBJECTIVES: To evaluate the impacts of two pharmaceutical cost containment policies-financial incentive for physicians to reduce their prescription drug expenditures and lump-sum drug price cut implemented in Oct. 2010 and Apr. 2012 respectively- on prescription drug expenditures from 2009 to 2012 in the national health insurance system of Korea. **METHODS:** Claims data for outpatient services in a random sample of 1,625 clinics were drawn from the national health insurance database between 2009 and 2012. Segmented regression analyses of interrupted time series were used to evaluate changes in prescription drug expenditures and non-drug expenditures per claim for selected common diseases – gastric ulcer & gastro-oesophageal reflux disease (adults), acute upper respiratory infection (URI) (adults/children), and acute lower respiratory infection (LRI) (adults/children). **RESULTS:** Prescription drug expenditures increased immediately after the implementation of financial incentive program in gastric ulcer & gastro-oesophageal reflux disease and LRI in adults. Monthly trends of prescription drug expenditures significantly decreased after the policy in all diseases analyzed. Lump-sum drug price cut suddenly dropped prescription drug expenditures. However, monthly trends of drug expenditures significantly increased after that. Neither of the two policies has changed the level or trend of non-drug expenditures. **CONCLUSIONS:** Financial incentive to physicians for reducing prescription drug costs was associated with decreased trends of prescription drug expenditures without increasing non-drug expenditures. Drug price cut led to instant reductions of prescription drug expenditures, however, it increased the monthly trends of prescription drug expenditures after the sudden reduction. The differential effects of two policies provide implications for pharmaceutical cost containment strategies in health insurance system.

PHP26

INSIGHTS IN EUROPEAN DRUG SHORTAGES: A SURVEY OF HOSPITAL PHARMACISTS

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OBJECTIVES: Drug shortages are a complex and global phenomenon. When a drug cannot be delivered at the moment of patient demand, every stakeholder in the health care system is affected. **METHODS:** This study aims to investigate the characteristics, clinical impact, financial impact and management of drug shortages in European hospital pharmacies. An online survey was designed based on literature and interviews with Belgian pharmacists. The online survey was sent to subscribers of Hospital Pharmacy Europe between June and September 2013. Descriptive statistics of the respondent's answers were calculated. **RESULTS:** One hundred sixty-one respondents were considered in this study. Results show variations between drug shortage characteristics in European regions and countries. Besides manufacturing problems, a role for European and national policy measures related to the market access and trade of pharmaceuticals, such as tendering and parallel trade, are discussed as a root cause for drug shortages. Further, respondents indicate drug shortages in Europe are associated with clinical risks for patients such as medication errors, a financial burden on hospitals and increased workload for the hospital pharmacy. The median number of hours spent to the management of drug shortages by hospital pharmacists was estimated to be 12.85hours/week. While pharmaceutical companies and wholesalers already assist the hospital pharmacy in the management of shortages, a role is still reserved for the government. **CONCLUSIONS:** This study showed drug shortages have a significant effect on hospitals, their personnel and patients. Mandatory notification in advance and centralized information is proposed to reduce workload for hospital pharmacists. Further, this will allow early anticipation of drug shortages and facilitates mitigation of the clinical impact on patients. Monitoring of the effect of policy measures on the availability of drugs is required to reveal and tackle the root causes behind drug shortages.

PHP27

AN UPDATE ON HOW NICE MANAGE OFF-LABEL COMPARATORS

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OBJECTIVES: NICE in the UK has a remit to compare new interventions to established care, which could include off-label medication. The objective was to update the assessment of how frequently NICE request off-label comparators and the subsequent implications. **METHODS:** All NICE single technology appraisal (STA) scopes from 01/01/08 to 18/12/13 were reviewed. Off-label comparators were identified as those that were being used outside their licence according to the Electronic Medicines Compendium. In cases where off-label comparators were requested in the scope, the manufacturer's submission, the Evidence Review Group report and the final NICE guidance were reviewed to ascertain the outcome of this request. **RESULTS:** Of 111 completed STAs reviewed, the scopes of 31 (27.9%) requested comparison to at least one off-label comparator; the proportion has been relatively stable over time. Since the previous analysis at the end of 2012, there has been a slight shift to more manufacturers not comparing to the requested off-label comparator (51.6% at end 2013 versus 45.8% at end 2012; driven by 80% of 2013 cases). NICE accepted the decision to not compare to the off-label agent in a much higher proportion of appraisals at the end of 2013 (81.3%) versus at the end of 2012 (63.6%). Two appraisals where NICE had originally rejected the new technology in favour of an off-label comparator had been re-appraised and NICE reversed their decision and now recommend the new interventions (TA274 and TA301). Overall however, NICE have rejected 8 new interventions (25.8% of scopes with off-label comparators requested) between 2008 and 2013 for not being cost-effective, thereby indirectly recommending the off-label alternative. **CONCLUSIONS:** NICE have rejected new interventions in favour of off-label comparators. However, there may be a recent shift towards more manufacturers choosing not to compare to the requested off-label comparator and for NICE to accept this decision.

PHP28

POINT OF CARE TESTS: THE LONG AND WINDING ROAD TO REIMBURSEMENT IN THE UNITED STATES AND CANADA

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OBJECTIVES: Market access for innovative new technologies can be complex and time consuming. As cost-containment pressures intensify, evidentiary hurdles to justify new point-of-care (POC) tests continue to grow. Decentralized health care decision making also can be a significant hurdle. This study aimed to characterize the process and identify challenges for health technology assessment (HTA), pricing, reimbursement, and market access for a new POC test in the United States (US) and Canada. **METHODS:** We conducted desktop research of published literature, HTA reports, and third-party websites to identify the critical path and data most valuable to reimbursement decision making. We also conducted qualitative one-on-one interviews with payer decision makers in the US (15 payers) and Canada (1 payer advisor and 2 laboratory directors). **RESULTS:** Reimbursement is critical to rapid adoption of new technologies. There are multiple appropriate access pathways for various theatres of care (e.g., outpatient office/clinic, inpatient, emergency), all with varying requirements and value drivers. Payment for new diagnostic tests typically is handled regionally or locally; treating physicians and medical societies can influence these budget decisions. Test reimbursement processes may differ for inpatient versus outpatient use. Currently, the evidence hurdle for a POC test is not as high as for prescription medicines. **CONCLUSIONS:** Market access for a POC test is variable; adequate data to meet decision makers' needs is not well understood. No roadmap exists for navigation of the critical path for POC tests, and evidence requirements in the US and Canada are not well established. Access for a POC test will be complex; regardless of pathway, decisions regarding reimbursement and adoption of new technology are diverse and dispersed across and within countries with varying levels of required evidence.

PHP29

REAL LIFE IMPACT OF EXTERNAL REFERENCE PRICING IN EUROPE USING A SIMULATION MODEL

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OBJECTIVES: External reference pricing (ERP) is one of the most common cost-containment tools used to reduce prices for in-patent pharmaceuticals in European Union Member States. The objective of this project was to assess the real life impact of ERP in Europe using a simulation model. **METHODS:** A simulation model (developed for the EU Commission) was built to simulate the evolution of drug price over time through the ERP process. Real-life cases of medicinal products were randomly selected from medicines approved via the European Medicines Agency centralised procedure between 2000 and 2012 and including off-patent/in-patent drugs, cheap/medium-priced/expensive drugs, and orphan/non orphan drugs. IMS price database was selected as source of information, covering 26 European countries and including 12 years history price data. Model outcomes were compared to actual recorded prices and interpretation of outcomes was enlightened with the French and Scottish Health Technology Assessment (HTA) reviews. **RESULTS:** Fifty three medicines were selected for the analysis of real-cases. The following trends were observed: 1) When a product was initially recognized as an innovative product by HTA, actual price of this product appeared to consistently achieve a higher price than the ERP model price; 2) Actual price of the product tended to become lower than ERP model price over time when a product had extension of indications over time and generated high revenue; 3) Low GDP countries tended to be the last to achieve drug entry, suggesting the use of launch sequence strategy from the marketing authorization holder. **CONCLUSIONS:** The ERP model seemed to well predict actual prices. ERP seems to be modulated by drug innovation as acknowledged by HTA. More research is needed to understand the role of launch sequence for price optimization.

PHP30

COMPARISON OF PREDICTABILITY OF MEDICAL DEVICE REVIEW PERIOD IN THE UNITED STATES AND JAPAN

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OBJECTIVES: "Device Lag" is one of the most imminent issues for medical device industry to focus for the coming years. In order to effectively approach this structured problem, the recognition of related facts and figures are the key factors. The purpose of this research is to provide the analysis of predictability difference among medical device categories in US and Japan and its background. **METHODS:** Based on the database of US PMA approved medical devices from 2004 to 2013 and new medical devices approved in Japan since April 2007, which point was 3 years from the establishment of PMDA (Pharmaceutical and Medical Device Agency) in Japan, 260 devices in US and 101 devices in Japan were identified for the analysis of predictability. Statistical values related to regulatory review period were compared between US and Japan and also among the device categories. **RESULTS:** By two-sided paired t test New Medical Device regulatory review period (15 devices approved in both countries) had no significant difference (P value>0.9). Among the product categories in the United States, for the identification of which the advisory committee classification was used, the standard deviation of FDA review time was the smallest in the fields of Radiology (202.5 days) followed by Microbiology (211.0 days) and Pathology (246.6 days) and the largest in the fields of General & Plastic